

K102901

OCT 27 2010

## **Section 1**

### **510(k) Summary**

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**Submitter Information**

OCT 27 2010

<b>Submitter:</b>	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371 ph: (330) 425-1313 fax: (330) 963-0749
<b>Contact:</b>	Douglas J. Thistlethwaite
<b>Date:</b>	September 27, 2010

**Device Name**

<b>Classification Name:</b>	System, Imaging, Pulsed Doppler, Ultrasonic
<b>Classification Number:</b>	90-IYN
<b>Trade/Proprietary Name:</b>	HITACHI HI VISION Avius Diagnostic Ultrasound Scanner
<b>Predicate Device(s):</b>	HITACHI HI VISION Preirus Diagnostic Ultrasound Scanner K093466

**Device Intended Use**

The HI VISION Avius is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal Cephalic, Adult Cephalic, Endoscopy, Intra-luminal, Gynecology, Urology and Laparoscopic clinical applications.

The Modes of Operation of the HI VISION Preirus are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, and Real Time Tissue Elastography.

**Device Description****Function**

An ultrasound system consists of the following:

- Ultrasound transducer(s) to generate the transmitted ultrasound energy and detect the reflected echoes
- A computer system to control the transducer and analyze the signals resulting from the reflected echoes
- A video monitor with optional image recorder to display the computed image or derived Doppler data

**Scientific Concepts**

An acoustic wave is a mechanical perturbation of a medium which passes through a given medium at a fixed velocity. The rate at which the particles in the medium vibrate in the disturbance is the frequency of the wave, and is measure as cycles/second, or hertz (Hz). Frequencies above 20 kHz are not audible, and above this frequency, the acoustic energy is known as ultrasound. For the purposes of medical ultrasound imaging, frequencies in the range of 1-20 MHz are utilized.

The ultrasound waves comprising a beam travel in as straight line in homogeneous media. When an ultrasound wave reaches an interface between two media of different impedances, a portion of the beam energy may pass through the boundary (transmission), and a portion may be reflected. The direction of propagation of the transmitted beam is determined by the angle of incidence of the incident beam upon the boundary, and differences (if any) in the speed of sound in the two media. The direction of reflection is determined solely by the angle of incidence upon the boundary. The relative strength of the reflected wave depends upon the differences in the impedances between the two media. Reflection at a boundary between soft tissue and bone, as an example, involves a large impedance difference, and results in a relatively strong reflected echo. Reflection at a boundary between two soft tissue-types with a relatively small impedance difference, on the other hand, results in a relatively weak reflected echo.

The ultrasound transducer, when operating in pulsed mode, periodically emits an ultrasound burst at a predetermined rate described as the pulse repetition frequency (PRF). During the time duration that the transducer is not transmitting ultrasound energy, it may act as a receiver for the reflected ultrasound energy. Since the speed of propagation of ultrasound in tissues is estimated as 1540m/sec, the time elapsed between transmission of a pulse and receipt of an echo may be used to estimate the distance from the transducer to the tissue structure giving rise to the reflected echo. The relative strength of the reflected echo can be used to determine the brightness of display of the reflected echo or strength of derived Doppler signal.

### ***Physical and Performance Characteristics***

The principle of operation of ultrasound imaging involves generation of an ultrasound wave with an electric signal applied to a transducer, direction of the resulting ultrasound wave into the tissue of the body, and reception and analysis of the echoes reflected back to the same or an adjacent transducer from the various tissues along the path of the ultrasound wave.

### **Device Technological Characteristics**

The technological characteristics of this device are identical to the primary predicate device. The control and image processing hardware and the base elements of the system software are identical to the predicate device. See Section 4 – Predicate Device Comparison.

### **Conclusions**

It is the opinion of Hitachi Medical Systems America, Inc. that HITACHI HI VISION Avius Diagnostic Ultrasound Scanner is substantially equivalent to the predicate devices. In addition, we have concluded that the subject system is substantially equivalent with respect to safety, effectiveness, and functionality to the HI VISION Preirus Diagnostic Ultrasound Scanner K093466 with the exception of the new transmitter. The Product Specification for new transmitter is included in Section 3 – General Device Description and the validation is included in Section 6 – Clinical Safety & Effectiveness.

### **Attachment**

ATTACHMENT	POSITION
Declaration of Conformity with Design Controls	1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Mr. Doug Thistlewaite  
Manager, Regulatory Affairs  
Hitachi Medical Systems America, Inc.  
1959 Summit Commerce Park  
TWINSBURG OH 44087-2371

OCT 27 2010

Re: K102901

Trade/Device Name: HI VISION Avius Diagnostic Ultrasound Scanner  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, and ITX  
Dated: September 27, 2010  
Received: September 30, 2010

Dear Mr. Thistlewaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the HI VISION Avius Diagnostic Ultrasound Scanner, as described in your premarket notification:

Transducer Model Number

EUP-B512  
EUP-B514  
EUP-C511  
EUP-C514  
EUP-C516  
EUP-C524  
EUP-C532  
EUP-C715  
EUP-CC531

EUP-CV524  
EUP-CV714  
EUP-ES52E  
EUP-ES52M  
EUP-F334  
EUP-F531  
EUP-L52  
EUP-L53  
EUP-L53L

EUP-L54MA  
EUP-L65  
EUP-L73S  
EUP-L74M  
EUP-LV74  
EUP-O53T  
EUP-054J  
EUP-OL334  
EUP-R54AW-19, -33

EUP-S50A  
EUP-S52  
EUP-S70

EUP-U533  
EUP-V53W  
EUP-VV531

EUP-VV731

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

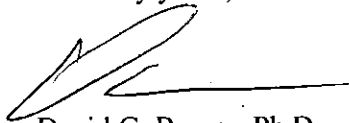
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,



David G. Brown, Ph.D.  
Acting Director  
Division of Radiological Devices  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure(s)

## Indications for Use

K102901

OCT 27 2010

510(k) Number (if known):

Device Name: **HI VISION Avius Diagnostic Ultrasound Scanner**

### Indications For Use:

The HI VISION Avius is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal Cephalic, Adult Cephalic, Endoscopy, Intra-luminal, Gynecology, Urology and Laparoscopic clinical applications.

The Modes of Operation of the HI VISION Avius are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, and Real Time Tissue Elastography.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

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510K

K102901

System: **DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM**  
**HI VISION Avius**

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic	P	P	P		P	P	P
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic	P	P	P		P	P	P
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Ph
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)	Pg	Pg	Pg	P	Pg	Pg	Pg
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, 3D Imaging, Real Time Tissue Elastography, Torapezoid, Contrast, Oblique, High Compound imaging, Omni Directional M-mode, Wide View, Tissue Doppler imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.


Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-B512

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Contrast, High Compound imaging, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

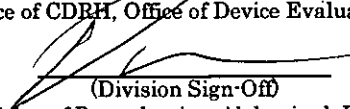
Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number: K102901



# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-B514

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Contrast, High Compound imaging, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

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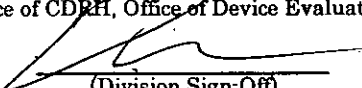
Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-C511

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P		P	P	P
	Cardiac Pediatric	P	P	P		P	P	P
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

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\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Contrast, High Compound imaging,  
Omni Directional M-mode, Wide View

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures  
(including amniocentesis).

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(excluding neurosurgery and laparoscopic procedures).

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Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius

Transducer: EUP-C514

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

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\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Contrast, High Compound imaging,  
Omni Directional M-mode, Wide View

## Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-C516

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

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\*\*Amplitude Doppler, Harmonic Imaging, Contrast, High Compound imaging,  
Omni Directional M-mode, Wide View

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Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-C524

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, High Compound imaging, Omni Directional M-mode, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-C532

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic	P	P	P		P	P	P
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography, High Compound imaging, Wide View

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.


Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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and Radiological Devices

510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-C715

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Contrast, High Compound imaging,  
Omni Directional M-mode, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures  
(including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-CC531

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography,

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-CV524

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	P	P	P		P	P	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, 3D Imaging, High Compound imaging, Omni Directional M-mode

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-CV714

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	P	P	P		P	P	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, 3D Imaging, High Compound imaging, Omni Directional M-mode

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-ES52E

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)	P	P	P	P	P	P	P
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Omni Directional M-mode, Tissue Doppler imaging

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-ES52M

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)	P	P	P	P	P	P	P
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Omni Directional M-mode, Tissue Doppler imaging

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: 15102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-F334

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic	P	P	P		P	P	P
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal	P	P	P		P	P	P
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-F531

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic	P	P	P		P	P	P
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal	P	P	P		P	P	P
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-L52

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography, Torapexoid, Oblique, High Compound imaging, Omni Directional M-mode, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-L53

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography, Torapezoid, Oblique, High Compound imaging, Wide View

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number: K102901



# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-L53L

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography, Torapexoid, Oblique, High Compound imaging, Wide View

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,  
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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-L54MA

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography, Torapezoid, Oblique, High Compound imaging, Wide View, Omni Directional M-mode

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,  
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510(k) Number: 14102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-L65

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography, Torapexoid, Oblique, High Compound imaging, Wide View, Omni Directional M-mode

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,  
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510(k) Number: 12102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-L73S

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography, Trapezoid, Contrast, Oblique, High Compound imaging, Omni Directional M-mode, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: 5102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-L74M

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography, Trapezoid, Contrast, Oblique, High Compound imaging, Omni Directional M-mode, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-LV74

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography, Torapexoid, Oblique, High Compound imaging, Omni Directional M-mode, 3D imaging

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-O53T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography, Torapexoid, Oblique, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-054J

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography, Torapexoid, Oblique, High Compound imaging, Omni Directional M-mode, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,  
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510(k) Number: K102901



# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-OL334

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic	P	P	P		P	P	P
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-R54AW-19, -33

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
Subscript "e": Includes imaging for guidance of transrectal biopsy.  
Subscript "f": Includes imaging for guidance of transvaginal biopsy.  
Subscript "g": For pediatric patients.  
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-S50A

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Contrast, Omni Directional M-mode, Tissue Doppler imaging

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-S52

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc	Pc	Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Omni Directional M-mode, Tissue Doppler imaging

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,  
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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-S70

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Contrast, Omni Directional M-mode, Tissue Doppler imaging

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-U533

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Ph
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography, Torapexoid, Oblique, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-V53W

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, Real Time Tissue Elastography,  
Contrast, High Compound imaging, Wide View

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures  
(including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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510(k) Number: K102901

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-VV531

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal	P	P	P		P	P	P
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler, Harmonic Imaging, High Compound imaging, 3D imaging

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: HI VISION Avius  
Transducer: EUP-VV731

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal	P	P	P		P	P	P
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K093466

\*Combination of each operating mode, B, M, PWD and Color Doppler.

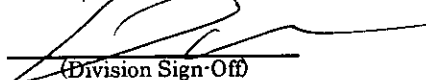
\*\*Amplitude Doppler, Harmonic Imaging, High Compound imaging, 3D imaging

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).  
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).  
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.  
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.  
Subscript "e": Includes imaging for guidance of transrectal biopsy.  
Subscript "f": Includes imaging for guidance of transvaginal biopsy.  
Subscript "g": For pediatric patients.  
Subscript "h": Includes imaging for guidance of transrectal biopsy.

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